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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,076	03/27/2002	James B. McCarthy	110.01270101	4527

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EXAMINER

HADDAD, MAHER M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/937,076	<b>Applicant(s)</b> MCCARTHY ET AL.	
	<b>Examiner</b> Maher M. Haddad	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-10,13,17-21,25,28,31,32,35 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-10,13,17-21,25,28,31,32 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/19/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 1, 4-10, 13, 17-21, 25, 28, 31, 32, 35 and 38 are pending.
2. Applicant's election with traverse of Group VII, claims 38-40 (now claim 38) drawn to a composition comprising a  $\beta$ 1 integrin inhibitor having the amino acid sequence OPPRAAIY (SEQ ID NO: 3) and a pharmaceutically acceptable carrier filed on 7/14/04, is acknowledged.

Applicant's traversal is on the grounds that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner. Applicant requests a rejoinder in pursuant to the "Guidance on Treatment of Product and Process Claims, in light of *In re Ochia*, *In re Brouwer* and 35 U.S.C(b)," O.G, 86. This is not found persuasive, the present application is a national phase application under 37 C.F.R. § 371 which has a lack of unity over art. Therefore, Applicant's inventions do not contribute a special technical feature when viewed over the prior art, Applicant's inventions do not have a single general inventive concept and so lack unity of invention as set forth in the previous Office Action. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1, 4-10, 13, 17-21, 25, 28, 31, 32 and 35 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claim 38 is under examination as they read on a composition comprising a  $\beta$ 1 integrin inhibitor having the amino acid sequence OPPRAAIY (SEQ ID NO: 3) and a pharmaceutically acceptable carrier.
5. Sequence compliance: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence.

See page 36, lines 15-35 of the instant specification.

Applicant is reminded of the sequence rules which require a submission for all sequences of 10 or more nucleotides or 4 or more amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

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6. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications 60/167,538 and 60/125,634 upon which priority is claimed fails to provide adequate support for SEQ ID NO: 3 of this application. The filing date of the instant applicant is deemed to be 03/22/1999.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

8. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising  $\beta$ 1-integrin inhibitor consisting of the amino acid sequence QPPRAAIY (SEQ ID NO: 3) and a pharmaceutically acceptable carrier does not reasonably provide enablement for a composition comprising  $\beta$ 1-integrin inhibitor "having" the amino acid sequence QPPRAAIY (SEQ ID NO: 3) and a pharmaceutically acceptable carrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

The term "having" in claim 38 is open ended and extend the peptide of SEQ ID NO: 3 to include additional amino acids on either or both N- and C- terminal. The claim as written encompasses a broad genus of amino acid sequences with an unlimited number of possibilities with regard to the length of the amino acid sequence. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological activities. Because of the lack of sufficient guidance and predictability in determining which modifications would lead to the inhibition of  $\beta$ 1 integrin inhibition and that the relationship between the peptide and its activity was not well understood. It would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of any peptide "having" QPPRAAIY. Without sufficient guidance, the changes which can be made in the structure of "peptide" and still provide inhibition of  $\beta$ 1 integrin is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

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9. Since the filing date of the instant applicant is deemed to be 03/22/1999, therefore the following rejection is applied.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

11. Claim 38 is rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/37669 (IDS Ref. 11).

The '669 publication teaches composition comprising  $\beta$ 1-integrin inhibitor having the amino acid sequence QPPRAAIY. The reference peptide is a Trp-9-Tyr which has the alanine knockout analog having the amino acid sequence WQPPRAAIY (see referenced SEQ ID NO: 8 and published claim 15 in particular). The '669 publication teaches that the reference cells were preincubated with 0.5 mg/ml of peptide (see page 18, line 1-2 in particular) and that peptide was diluted to 3-5ug/ml in PBS containing 1mM CaCl<sub>2</sub>, MgCl<sub>2</sub> (see page 11, lines 30-33 in particular) which is also consider to be a pharmaceutically acceptable carrier.

The term "having" in instant claim 38 is open-ended. It would open up the claim to include the reference 9 amino acid sequence.

The reference teachings anticipate the claimed invention.

12. No claim is allowed.

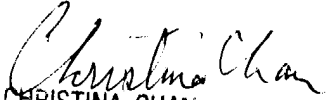
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 4, 2004

  
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